Management Review Meeting -9  
Sri Nathella Sampathu Chetty Clinical laboratory  
Review of July to December audit cycle-II-2010, Dated 12.2.2011  

Attendance: By list (Sheet enclosed). The representations were from the SN main lab for hematology and clinical pathology, routine biochemistry, sp. biochemistry, Microbiology and serology, Histopathology, cytogenetics and the support services, CSFU, HRD, Commercial, Housekeeping, Biomedical, and all Internal auditors.  
The stipulated agenda points presented by the Quality Manager, Dr. N. Angayarkanni.  

Discussions were held on the following agenda points  
1. Follow up of previous management review  
2. Status of Corrective and Preventive Actions taken (CAPA)  
3. Report from Managerial and supervisory personnel of each of the lab on QC/Measures  
4. Out come of recent internal audits, NC’s.  
5. Assessments of external bodies.  
6. Outcome of Quality Control: External/Internal/Daily of each lab: EQAS, ILQC.  
7. Volume and type of work undertaken.  
8. Feedback including complaints and other relevant factors for Internal and external  
9. Quality Indicators for monitoring the laboratories contribution to patient care  
11. Monitoring Turn around time.  
12. Continual improvements.  
14. Points for Discussion for action  
The details on each of the points are self explanatory on the slides enclosed.  

1. Key Points  
1. The Second internal audit July to December – 10 has been conducted by the trained and approved internal auditors. The entire NC raised in the internal audits is closed.  

Audit Team Members and Audited labs:  
1. Dr. DG - QM office, Central Sterilization Facility Unit, observer-Ms. Margarita  
2. Dr. B. Mahalakshmi -Hematology and Clinical pathology - observer-Ms. Margarita  
3. Ms. R. Punitham - Microbiology and serology  
4. Ms. K. Vanitha-. Biochemistry, Front office and pre analytical area  
5. Ms. B. Mohanambal – Cyto genetics observer- Ms. Prasanna.  
6. Ms. R. Selvi – Histopathology, observer- Ms. Prasanna  
8. Ms. Soumya - HRD
Number of tests accredited as in the Scope:
Clinical Pathology: 23; Clinical Hematology: 20; Clinical Biochemistry: 27;
Clinical Microbiology: 28; Clinical Histopathology: 15; Cytopathology: 8.
Histopathology: 4 tests to be removed from the scope. 1. Elastic stain, 2. Giemsa stain
3. Fontana Masson stains 4. Toludine blue stain. Will be done in the renew of application
in april 2011. Till then it can be continued.

2. New signing Authority
   1. Dr. Doreen Gracias name included in the Clinical Biochemistry. The communication
      sent last MR Meeting minutes.

3. New post created
   1. The technical staff number is adequate.
   2. Two new senior technicians appointed in Clinical lab.

4. Promotions: No promotions.

5. Reporting system
   a. Progress in HMS:
      1. Microbiology and Serology – HMS implemented for bacteriology.
      2. Histopathology – HMS has been implemented.
      3. Interfacing with HMS reporting system implemented on august 2010 and monitoring
         under the IT at clinical lab.

6. Version numbers of documents revised in 2010 (July to December)
   1. Requisition form for eye bank specimens for Microbiology and Serology
      F/SNSC/MS/EBRF/1.1
   2. Consent form for HIV testing F/SNSC/MS/CFH/09/1.1

7. The QC reports of all the labs are satisfactory overall and CAPA filed as applicable.

8. The measures – overall is satisfactory and CAPA is filed wherever there is a fall.
   Microbiology lab accepted to raise their post analytical objectives of their measures fall from
   75% to 53%. Corrective action taken.

9. New machineries were installed in July to December periods. No major breakdown and Turn
   around time is maintained for investigations.
   a. Microtome (Leica RM2245) at Pathology.
   b. Sheared machine implemented for obsolete copies to destroy.

10. Continual Improvement
    The continual improvement presented in MR-Meeting.
    a. Completion of major implementation of interfacing with HMS.
    b. Introduced of bar-coding system at main lab.
    c. Increased statistics number of investigations 2009: 93,942 for 2010: 1,09,41
    d. New posts have been created (Two Senior technicians).
e. New instruments were installed (Microtome, Shredder).

f. MIS made more comprehensive to inform the laboratory activities to the management.

g. New measures created for histopathology in the analytical area.

h. Interfacing the ISO 15189:2007 standard with NABH.

11. Feedback analysis

1. Analysis of internal customer feedback: revealed that the statistics with regards to the no of forms issued/collected was maintained. The measure were (July to December) 83.0% at main lab for the internal customer (consultant, physician, nursing and surgery fixing centers).

12. Vendor Evaluations

1. The approved vendor list prepared by the commercial after evaluation (July to December 2010) was presented the same will be circulated to all labs.

13. Points for other information


15. The non-technical and the technical training schedule in all the labs were satisfactory. Henceforth the evaluation to be strictly documented.

16. Outsourced test of HbA1C, Microalbumin were started in Biochemistry department but are not in scope of NABL.

17. Copy reports are issued in the lab enquiry on patient request, without sending the patient to each lab.

18. Tamil Nadu Pollution control Board certificate for disposal of waste has been received the validity is till 2012. Waste disposal is done by G.J multiclave it will continued.

Follow up:

- To improve the inventory control, cost per analysis. -- **Revision in the cost of the test is implemented**
- Strategies to improve the collections and the number of investigations done-- **Brochure is prepared**
- JKCN and NSN will be audited as part of internal audit henceforth.-- **NABH audit**
- To make the HMS system complete.-- **IT will again be informed on a an action plan**
- Interface system to be implemented -- **Would be completed**
Reminders:

- Reviews: of contracts / records / SOP/ Calibration plan / status documentation of the obsolete record shredded
- Continual improvement and preparation of Quality Plan 2012
- Inputs for vendor evaluation / material specification sheet to be prepared for the year 2011-2012
- Interaction with clinical consultants to be documented and sent to QM for record.
- Protocols to be followed on inclusion of new tests and included in the collection manual.
- Safety measures to be reviewed and training implemented/evaluated
- MIS meeting for interaction with the management expanded.
- CAPA: Effectiveness of preventive actions to be evaluated
- Quality Check of stored specimen to be documented
- Training: Skill / knowledge + evaluation

Thank You

Dr. N. Angyarkanni,  
Quality Manager,  
Medical Research Foundation  
SNSC Laboratory  
Chennai – 600 006.

Date: 18.2 .2011.

Forwarded by:  
Dr.S.B.Vasanthi  
Management Representative  
Medical Research Foundation  
SNSC Clinical Laboratory  
Chennai – 600 006.
Management Review Meeting -10
Sri Nathella Sampathu Chetty Clinical laboratory
Review of Jan to June audit cycle-I -2011
Dated 6.8.2011

Attendance: By list (Sheet enclosed). The representations were from the SN main lab for hematology and clinical pathology, routine biochemistry, sp. biochemistry, Microbiology and serology, Histopathology, cytogenetics and the support services, CSFU, HRD, Commercial, Housekeeping, Biomedical, and all Internal auditors.
The stipulated agenda points presented by the Quality Manager, Dr. N. Angayarkanni.

Discussions were held on the following agenda points
1. Follow up of previous management review
2. Status of Corrective and Preventive Actions taken (CAPA)
3. Report from Managerial and supervisory personnel of each of the lab on QC/Measures
4. Outcome of recent internal audits, NC’s.
5. Assessments of external bodies.
6. Outcome of Quality Control: External/Internal/Daily of each lab: EQAS, ILQC.
7. Volume and type of work undertaken.
8. Feedback including complaints and other relevant factors for Internal and external
9. Quality Indicators for monitoring the laboratories contribution to patient care
11. Monitoring Turn around time.
12. Continual improvements.
14. Points for Discussion for action

The details on each of the points are self explanatory on the slides enclosed.

Audit Team Members and Audited labs:
1. Dr. John Kenneth –Quality System
2. Dr. Sultana Furruqh –Clinical Biochemistry
3. Dr. Sangita Keskar – Clinical pathology and Hematology.
4. Dr. Ratna Rao – Clinical Microbiology
5. Dr. Ramesh Dawar – Histopathology and cytopathology

Key Points
1. The internal audit January to June –2011 has been conducted by the NABL technical assessors. Due to this internal audit was not done. The entire NC raised in the audits is

Issue Date 16.08.11 
Prepared & Issued by: Quality Manager : Dr.N.Angayarkanni
Approved by: Management Representative : Dr.S.B.Vasanthi
addressed and recommended for closure by the assessors. The same has been submitted to NABL office and the certificate is awaited. As the validity period as on 3.8.2011 is over logo is currently not in use.

**Number of tests accredited as in the Scope:**
The new revised scope submitted to the NABL. Once it is approved the total number will be given.

a. New tests added in the Microbiology: 6 test removed from the scope.
   (Chlamydia trachomatis, Adeno virus, HSV, Immuno fluorescence stain for HSV, Adeno virus. Included in the scope: Antibodies to HCV ELISA

b. Some of the test removed from the scope:
   a. Histopathology: 4 tests removed from the scope.
   b. Main lab: Ben Jones protein

Clinical Pathology: 22; Clinical Hematology:20 Clinical Biochemistry : 27; Clinical Microbiology : 22; Clinical Histopathology: 15; Cytopathology : 8.

2. **New signing Authority**
   2. Dr. Coral Miriam Magdalene name included in the Clinical Biochemistry. The communication sent. The auditor suggested giving few certificate and then they will recommend for future.

3. **New post created**
   3. The technical staff number is adequate.
   4. Six new senior technicians appointed in all labs.
   5. Two lab assistant posts converted in to technician post.

4. **Promotions** : No promotions.

5. **Reporting system**
   **Progress in HMS:**
   1. For copy report to all patients and use of HMS generated report for MRD will be taken up. The detail discussion had with MRO, DPS and IT department.
   The copy reports can be taken print out to all locations with and without logo.

6. **Version numbers of documents revised in 2011 (Jan to June)**

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Prepared & Issued by: Quality Manager : Dr.N.Angayarkanni

Approved by: Management Representative : Dr.S.B.Vasantha
1. Quarterly summary for the reporting to QM: SNSC/QREP/2011/isu-1.3

7. **The QC reports of all the labs are satisfactory overall and CAPA filed as applicable.**
8. **The measures** – overall is satisfactory and CAPA is filed wherever there is a fall. Corrective action taken.

9. **New machineries** were installed in January to June periods. No major breakdown and Turn around time is maintained for investigations.
   c. Bought new coagulometer (Stago) installed on 11.3.2011.

10. **Continual Improvement**
    The continual improvement presented in MR-Meeting.
    a. Interfacing of the Clinical Hematology, Clinical Biochemistry, Clinical Pathology results with HMS and specimen entry made by the system.
    b. Manual entry in the ledger and data entry in the computer system was reduced and automatic update with the systems lot of manual work has been reduced in clinical lab.
    c. Copy report will be given to the patient through DPS through lab enquiry.
    d. Five Senior technician post have been created by converting the Technician and lab assistant post based on Qualification and other eligibility.
    e. Basic health check for all lab staffs (NABH purpose).
    f. Introduced new test for Malarial parasite (Strip method).
    g. Bought new coagulometer (Stago)
    h. Abnormal DC’s are done by 2 technicians.
    i. Biorad quality control (EQAS) started for 2 coulters.
    j. Header and footer included for all the displays.
    k. ACE estimation the reagent volume reduced from 1000µl to 250µl with high sensitivity.
    l. From manual method to kit method introduced for Lactate and pyruvate.
    m. HPLC autoclaved milli Q water used for better resolution.
    n. Dade Machine Autoclaved water is used for analysis and pH checked everyday.
    o. Tubing check included in System check.
    p. Quality control two levels for glucose done at 3.00pm
    q. Accounts for QC aliquots.
    r. Sample cups used for glucose estimation. Now the fluoride tube is kept direct to the machine. Saved each cup money for Rs. 2.0
    s. Using closed container for 1% hypochloride.
    t. Updated lab profile in the website http://www.ilqabangalore.com/histo for uploading results of ILQA by Anand laboratory Bangalore

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**Issue Date 16.08.11**

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<td>Management Representative: Dr. S. B. Vasanthi</td>
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u. Generating separate typed report for frozen sections  
v. Separate record for cytology and histopathology correlation of specimens received  
w. Comparison of quality plan and continual improvement was done.

11. Feedback analysis  
2. Analysis of internal customer feedback: revealed that the statistics with regards to the no of forms issued/collected was maintained. The measure were (January to June) 86.6 % at main lab for the internal customer (consultant, physician, nursing and surgery fixing centers).

12. Vendor Evaluations  
1. The approved vendor list prepared by the commercial after evaluation (January to June 2011) was presented the same will be circulated to all labs.

13. Points for other information  
• The non-technical and the technical training schedule in all the labs were satisfactory. The evaluation done strictly and documented.

• Lactate and Pyruvate test from manual method to kit method were started in Biochemistry department but are not in scope of NABL.

• Copy reports are issued in the lab enquiry on patient request, without sending the patient to each lab.

• Tamil Nadu Pollution control Board certificate for disposal of waste has been received the validity is till 2012. Waste disposal is done by GJ multiclave it will continue.

Follow up: Yet to complete

• Strategies to improve the collections and the number of investigations done—

  Brochure is prepared for SNSC clinical laboratory and is yet to be approved.

• JKCN and NSN will be audited as part of internal audit henceforth.—

  NABH audit

• To make the HMS system complete.—Specimen entry through online is under monitoring.
Reminders:
- Reviews: of contracts / records / SOP/ Calibration plan / status documentation of the obsolete record shredded
- Inputs for vendor evaluation / material specification sheet to be monitored.
- Interaction with clinical consultants to be documented and sent to QM for record.
- Protocols to be followed on inclusion of new tests and included in the collection manual.
- Safety measures to be reviewed and training implemented/ evaluated
- CAPA: Effectiveness of preventive actions to be evaluated
- Quality Check of stored specimen is documented.
- Vaccination documents kept in each department.
- The next internal audit is due in December 2011.

Thank You

Forwarded by:

Dr. N. Angyarkanni,
Quality Manager,
Medical Research Foundation
SNSC Laboratory
Chennai – 600 006.

Dr. S.B. Vasanthi
Management Representative
Medical Research Foundation
SNSC Clinical Laboratory
Chennai – 600 006.

Date: 16.8.2011.